

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hu *et al.*

Appl. No.: 09/219,442

Filed: December 23, 1998

For: Vascular Endothelial Growth  
Factor 2 and Methods of Use

Confirmation No.: 4797

Art Unit: 1647

Examiner: Landsman, Robert S.

Atty. Docket: 1488.100000I/EKS/HCC

## Eleventh Supplemental Information Disclosure Statement

Under 37 C.F.R. § 1.97(b)

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. This Eleventh Supplemental Information Disclosure Statement is a continuation of Applicant's Tenth Supplemental Information Disclosure Statement filed on January 21, 2005 in connection with the above-captioned application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

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Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicant has checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

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- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

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☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$\_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office

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is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

- ☒ 6. In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents FP6 and FP9 cited on Form PTO/SB/08A:

Document FP6, WO 98/55619, is in a foreign language. An English language abstract of Document FP6 is attached as document NPL47 on accompanying Form PTO/SB/08B.

Document FP9, WO 00/73430 A3, is in a foreign language. An English language abstract of Document FP9 can be found on the front page of the patent.

- ☒ 7. Copies of documents FP1 to FP12 and NPL1 to NPL48 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents US1 to US13, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

- ☐ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

- ☐ 9. It is expected that the examiner will review the prosecution and cited art in the parent application no(s). \*\*\*Par Appl number TE\*\*\* in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art

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cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson  
Agent for Applicant  
Registration No. 47,473

Date:

2/3/06

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**ELEVENTH SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	09/219,442
Filing Date	December 23, 1998
First Named Inventor	Hu, Jing-Shan
Art Unit	1647
Examiner Name	Landsman, Robert S.
Attorney Docket Number	1488.1000001/EKS/HCC

Sheet 1 of 5

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Alderson, R.F., et al., "Vascular Endothelial Cell Growth Factor (VEGF)-2 Enhances the Development of Rat Photoreceptor Cells In Vitro," <i>Keystone Symposia, Ocular Cell &amp; Molec. Biol.</i> , pp. 32, Abstract No. 202, Association for Research in Vision and Ophthalmology (February 1999)	
	NPL2	Altshuler, D., et al., "Taurine promotes the differentiation of a vertebrate retinal cell type in vitro," <i>Development</i> 119:1317-1328, The Company of Biologists Limited (December 1993)	
	NPL3	Better, M., et al., "Escherichia coli Secretion of an Active Chimeric Antibody Fragment," <i>Science</i> 240:1041-1043, American Association for the Advancement of Science (1988)	
	NPL4	Böcker-Meffert, S., et al., "Erythropoietin and VEGF Promote Neural Outgrowth from Retinal Explants in Postnatal Rats," <i>Invest. Ophthalmol. Vis. Sci.</i> 43:2021-2026, Association for Research in Vision and Ophthalmology (June 2002)	
	NPL5	Colwell, D.E., et al., "Method for Generating a High Frequency of Hybridomas Producing Monoclonal IgA Antibodies," <i>Meth. Enzymol.</i> 121:42-51, Academic Press, Inc. (1986)	
	NPL6	Danis, R.P., et al., "Anti-angiogenic therapy of proliferative diabetic retinopathy," <i>Exp. Opin. Pharma.</i> 2:395-407, Ashley Publications Ltd. (March 2001)	
	NPL7	Eichmann, A., et al., "Avian VEGF-C: cloning, embryonic expression pattern and stimulation of the differentiation of VEGFR2-expressing endothelial cell precursors," <i>Development</i> 125:743-752, The Company of Biologists Limited (February 1998)	
	NPL8	Enholm, B., et al., "Vascular Endothelial Growth Factor-C: A Growth Factor for Lymphatic and Blood Vascular Endothelial Cells," <i>Trends Cardiovasc. Med.</i> 8:292-297, Elsevier Science Inc. (October 1998)	
	NPL9	Ferrara, N., et al., "The Vascular Endothelial Growth Factor Family of Polypeptides," <i>J. Cell. Biochem.</i> 47:211-218, Wiley-Liss, Inc. (1991)	
	NPL10	Ferrara, N., "Vascular Endothelial Growth Factor and the Regulation of Angiogenesis," <i>Recent Prog. Hormone Res.</i> 55:15-36, The Endocrine Society (March 2000)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>ELEVENTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	09/219,442
		Filing Date	December 23, 1998
		First Named Inventor	Hu, Jing-Shan
		Art Unit	1647
		Examiner Name	Landsman, Robert S.
		Attorney Docket Number	1488.1000001/EKS/HCC
Sheet	2	of	5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL11	George, D.G., <i>et al.</i> , "Chap. 12. Current Methods in Sequence Comparison and Analysis," in: <i>Macromolecular Sequencing and Synthesis, Selected Methods and Applications</i> , Schlesinger, A.M., ed., John Wiley & Sons, Inc., Hoboken, NJ, pp. 127-149 (1988)	
	NPL12	Gerhardinger, C., <i>et al.</i> , "Expression of Vascular Endothelial Growth Factor in the Human Retina and in Nonproliferative Diabetic Retinopathy," <i>Am. J. Pathol.</i> 152:1453-1462, American Society for Investigative Pathology (June 1998)	
	NPL13	Halin, C. and Neri, D., "Antibody-Based Targeting of Angiogenesis," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> 18:299-339, Begell House, Inc. (August 2001)	
	NPL14	Hannink, M., <i>et al.</i> , "Deletions in the C-Terminal Coding Region of the v-sis Gene: Dimerization Is Required for Transformation," <i>Molec. Cell. Biol.</i> 6:1304-1314, American Society for Microbiology (1986)	
	NPL15	Hirai, M., <i>et al.</i> , "Expression of Vascular Endothelial Growth Factors (VEGF-A/VEGF-1 and VEGF-C/VEGF-2) in Postmenopausal Uterine Endometrial Carcinoma," <i>Gynecol. Oncol.</i> 80:181-188, Academic Press (February 2001)	
	NPL16	Houck, K.A., <i>et al.</i> , "The Vascular Endothelial Growth Factor Family: Identification of a Fourth Molecular Species and Characterization of Alternative Splicing of RNA," <i>Molec. Endocrinol.</i> 5:1806-1814, Williams & Wilkins (1991)	
	NPL17	Joosten, V., "The production of antibody fragments and antibody fusion proteins by yeasts and filamentous fungi," <i>Microbial Cell Factories</i> 2:1-15, BioMed Central (January 2003)	
	NPL18	Kelley, M.W., <i>et al.</i> , "Regulation of Proliferation and Photoreceptor Differentiation in Fetal Human Retinal Cell Cultures," <i>Invest. Ophthalmol. Vis. Sci.</i> 36:1280-1289, Association for Research in Vision and Ophthalmology (June 1995)	
	NPL19	Longo, R., <i>et al.</i> , "Anti-angiogenic therapy: Rationale, challenges and clinical studies," <i>Angiogenesis</i> 5:237-256, Kluwer Academic Publishers (December 2002)	
	NPL20	Ngo, J.T., <i>et al.</i> , "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," in: <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz, Jr., K. and Le Grand, S., eds., Birkhäuser, Boston, MA, pp. 491-495 (January 1994)	

Examiner Signature		Date Considered	
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		First Named Inventor	Hu, Jing-Shan		
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Sheet	3	of	5	Attorney Docket Number	1488.100000I/EKS/HCC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL21	Pajusola, K., <i>et al.</i> , "FLT4 receptor tyrosine kinase contains seven immunoglobulin-like loops and is expressed in multiple human tissues and cell lines," <i>Cancer Res.</i> 52:5738-5743, American Association for Cancer Research (1992)	
	NPL22	Pajusola, K., <i>et al.</i> , "Two human FLT4 receptor tyrosine kinase isoforms with distinct carboxy terminal tails are produced by alternative processing of primary transcripts," <i>Oncogene</i> 8:2931-2937, Nature Publishing Group (November 1993)	
	NPL23	Rudikoff, S., <i>et al.</i> , "Single amino acid substitution altering antigen-binding specificity," <i>Proc. Natl. Acad. Sci. USA</i> 79:1979-1983, National Academy of Sciences (1982)	
	NPL24	Schlaeppli, J.-M., <i>et al.</i> , "Characterization of a new potent, in vivo neutralizing monoclonal antibody to human vascular endothelial growth factor," <i>J. Cancer Res. Clin. Oncol.</i> 125:336-342, Springer-Verlag (May 1999)	
	NPL25	Schratzberger, P., <i>et al.</i> , "Reversal of experimental diabetic neuropathy by VEGF gene transfer," <i>J. Clin. Invest.</i> 107:1083-1092, American Societies for Clinical Investigation (May 2001)	
	NPL26	Schulz-Key, S., <i>et al.</i> , "Ciliary Neurotrophic Factor as a Transient Negative Regulator of Rod Development in Rat Retina," <i>Invest. Ophthalmol. Vis. Sci.</i> 43:3099-3108, Association for Research in Vision and Ophthalmology (September 2002)	
	NPL27	Seigel, G.M., "The golden age of retinal cell culture," <i>Molec. Vis.</i> 5:4, Molecular Vision (April 1999)	
	NPL28	Skerra, A. and Plückthun, A., "Assembly of a Functional Immunoglobulin F <sub>1</sub> Fragment in <i>Escherichia coli</i> ," <i>Science</i> 240:1038-1041, American Association for the Advancement of Science (1988)	
	NPL29	Stacker, S.A. and Achen, M.G., "The Vascular Endothelial Growth Factor Family: Signalling for Vascular Development," <i>Growth Factors</i> 17:1-11, Harwood Academic Publishers (March 1999)	
	NPL30	Tischer, E., <i>et al.</i> , "Vascular Endothelial Growth Factor: A New Member of the Platelet-Derived Growth Factor Gene Family," <i>Biochem. Biophys. Res. Commun.</i> 165:1198-1206, Academic Press, Inc. (1989)	

Examiner Signature		Date Considered	
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		Filing Date	December 23, 1998		
		First Named Inventor	Hu, Jing-Shan		
		Art Unit	1647		
		Examiner Name	Landsman, Robert S.		
Sheet	4	of	5	Attorney Docket Number	1488.1000001/EKS/HCC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL31	Vale, P.R., et al., "Percutaneous Electromechanical Mapping Demonstrates Efficacy of pVGL1 (VEGF2) in an Animal Model of Chronic Myocardial Ischemia," <i>Circulation Suppl.</i> 100:I.22, Abstract No. 109, American Heart Association Inc. (November 1999)	
	NPL32	Vale, P.R., et al., "Randomized, Single-Blind, Placebo-Controlled Pilot Study of Catheter-Based Myocardial Gene Transfer for Therapeutic Angiogenesis using Left Ventricular Electromechanical Mapping in Patients With Chronic Myocardial Ischemia," <i>Circulation</i> 103:2138-2143, American Heart Association Inc. (May 2001)	
	NPL33	van der Flier, M., et al., "Antibody neutralization of vascular endothelial growth factor (VEGF) fails to attenuate vascular permeability and brain edema in experimental pneumococcal meningitis," <i>J. Neuroimmunol.</i> 160:170-177, Elsevier B.V. (March 2005)	
	NPL34	Verma, I.M. and Somia, N., "Gene therapy - promises, problems and prospects," <i>Nature</i> 389:239-242, Macmillan Publishers Ltd. (September 1997)	
	NPL35	Walsh, D.A., "Angiogenesis and arthritis," <i>Rheumatology</i> 38:103-112, British Society for Rheumatology (February 1999)	
	NPL36	Winkler, K., et al., "Changing the Antigen Binding Specificity by Single Point Mutations of an Anti-p24 (HIV-1) Antibody," <i>J. Immunol.</i> 165:4505-4514, The American Association of Immunologists (October 2000)	
	NPL37	Yourey, P.A., et al., "Vascular Endothelial Cell Growth Factors Promote the <i>In Vitro</i> Development of Rat Photoreceptor Cells," <i>J. Neurosci.</i> 20:6781-6788, Society for Neuroscience (September 2000)	
	NPL38	Yourey, P.A., et al., "Vascular Endothelial Cell Growth Factors Promote the <i>In Vitro</i> Development of Rat Photoreceptor Cells," <i>Molec. Biol. Cell.</i> 10:39a, Abstract No. 227, American Society for Microbiology (November 1999) and 39 <sup>th</sup> Ann. Meeting of the American Society of Cell Biology, Washington, DC, held December 1999)	
	NPL39	NCBI Entrez, Accession No. AF010302, Mandriota S.J. and Pepper, M.S. (first available and last updated 1997)	

Examiner Signature		Date Considered	
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Sheet 5 of 5

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL40	NCBI Entrez, Accession No. S08167, Paulsson, G. <i>et al.</i> (first available 1993 and last updated March 2005)	
	NPL41	NCBI Entrez, Accession No. AAW27553, Han, Z. (first available February 2005 and last updated September 2005)	
	NPL42	Copy of International Search Report for International Application No. PCT/US02/26246, mailed May 21, 2003, United States Patent & Trademark Office, Washington, DC	
	NPL43	Copy of Supplementary Partial European Search Report for European Application No. 01963814, mailed July 14, 2004, European Patent Office, Munich, GE	
	NPL44	Copy of Supplementary Partial European Search Report for European Application No. 02726730, mailed August 4, 2004, European Patent Office, Munich, GE	
	NPL45	Copy of Supplementary Partial European Search Report for European Application No. 02721715, mailed October 22, 2004, European Patent Office, Munich, GE	
	NPL46	Copy of Supplementary Partial European Search Report for European Application No. 02721715, mailed January 10, 2005, European Patent Office, Munich, GE	
	NPL47	Dialog File 351, Accession No. 12299390, WPI English language abstract of WO 98/55619 (Document FP6 listed on accompanying SB/08A)	
	NPL48	Breier, G. <i>et al.</i> , "Expression of vascular endothelial growth factor during embryonic angiogenesis and endothelial cell differentiation," <i>Development</i> 114:521-532, The Company of Biologists Limited (1992)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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